

IN THE UNITED STATES DISTRICT COURT  
**FOR THE EASTERN DISTRICT OF VIRGINIA**  
Alexandria Division

BOND PHARMACY, INC., d/b/a AIS )  
HEALTHCARE, )  
Plaintiff-Counter ) Case No. 1:22-cv-01343-CMH-IDD  
Defendant, )  
v. )  
ANTHEM HEALTH PLANS OF )  
VIRGINIA, INC., d/b/a ANTHEM )  
BLUE CROSS AND BLUE SHIELD, )  
Defendant- )  
Counterclaimant. )

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**PLAINTIFF/ COUNTER-DEFENDANT BOND PHARMACY, INC., d/b/a  
AIS HEALTHCARE'S MEMORANDUM IN SUPPORT OF ITS  
MOTION FOR SUMMARY JUDGMENT**

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2	November 2020 Amendment	AIS00000663-72
3	April 2021 Amendment	ANTM R 00042363-72
4	December 2021 Amendment	AIS00030318-27
5	Deposition Tr. Aborne	N/A
6	Deposition Tr. Cahoon	N/A
7	Deposition Tr. Castellanos	N/A
8	Deposition Tr. Forshage	N/A
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28	Email from N. Oser to P. Henning (July 25, 2019)	ANTM 00024287-89
29	Email from S. Castellanos to P. Henning (Aug. 8, 2019)	ANTM_00011968-72
30	Anthem Clinical UM Guidelines	AIS00080520-28
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32	Email from P. Henning to Anthem (June 25, 2019)	ANTM R 00010450
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<b>49</b>	<i>See Department of Justice, 14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak (Dec. 17, 2014), available at <a href="https://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis">https://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis</a> (last visited September 20, 2023).</i>	N/A
<b>50</b>	Am. Pharmacists Assoc., <i>Frequently Asked Questions About Pharmaceutical Compounding</i> , available at <a href="https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs">https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs</a> (last visited September 20, 2023).	N/A
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<b>52</b>	Becker's ASC Rev., <i>Insurer under fire for millions in unpaid claims</i> , available at <a href="https://www.beckersasc.com/asc-coding-billing-and-collections/insurer-under-fire-for-millions-in-unpaid-claims.html">https://www.beckersasc.com/asc-coding-billing-and-collections/insurer-under-fire-for-millions-in-unpaid-claims.html</a> (last visited November 21, 2023)	N/A

Plaintiff/Counter-Defendant Bond Pharmacy, Inc., d/b/a AIS Healthcare (“AIS”), submits this Memorandum in Support of Summary Judgment against Anthem Health Plans of Virginia, Inc., d/b/a Anthem Blue Cross and Blue Shield (“Anthem”).

## **INTRODUCTION**

Anthem is one of the world’s largest health insurance companies, with billions of dollars in revenues. This action arises from Anthem’s wrongful effort to achieve even higher profits by renouncing its contractual payment obligations to AIS for home infusion therapy – a.k.a., “HIT” – that AIS has provided to Anthem’s members for years. Now, after the parties have engaged in extensive discovery, including over a dozen depositions and producing thousands of pages of documentary evidence, the record is clear: Anthem has breached the parties’ agreement by failing to pay AIS for providing Anthem members with its complex, world class care. AIS is therefore entitled to summary judgment on its breach of contract claim against Anthem as well as on Anthem’s reflexive and meritless counterclaim against AIS and boilerplate affirmative defenses.

AIS is a private compounding pharmacy with two state-of-the-art facilities in Texas and Mississippi. It is the leading provider of highly-specialized (and -regulated) intrathecal HIT services. HIT is a treatment of last resort reserved for the nation’s sickest patients who would otherwise remain confined to a hospital bed or on oral opioids at the mercy of their well-known devastating side effects. To provide this life-enhancing and life-saving therapy, AIS dispenses custom medications to patients with intrathecal pumps that continuously infuse – that is, “administer” – medications directly to a patient’s spinal column.

AIS has invested substantial resources to provide this therapy safely and effectively, which are necessary because its medications are administered directly into a patient’s spinal column where there is no effective immune system. AIS also spends significant resources to

ensure that its medications will remain sterile, stable and effective in the patient’s pump for up to 180 days. While these patients are on AIS’s medications, they also necessarily remain under AIS’s care as AIS remains responsible for the medication administered through their pumps. Accordingly, AIS maintains nurses, pharmacists, and a 24/7-staffed call center to provide ongoing access to care and services for its patients.

Recognizing the substantial value and quality of AIS’s therapy, Anthem entered a provider agreement with AIS in 2020 (“2020 Provider Agreement”) for AIS to provide its specialized HIT services and drugs to its members. Anthem agreed to pay AIS according to the “per diem reimbursement model” established by the National Home Infusion Association (“NHIA”) and incorporated into the parties’ agreement. Under this model, AIS may bill for each day a given patient is provided access to its prescribed therapy – that is, AIS’s medication and services, including around-the-clock support. For patients using intrathecal pumps, the per diem applies daily because AIS’s medication is administered on a continuous 24/7 basis.

Unfortunately, as soon as the parties signed the 2020 Provider Agreement, Anthem immediately reneged on the parties’ deal. In what has become a standard national playbook for Anthem, Anthem used an ever increasing series of unilateral amendments, improper claims denials, and outright refusals to pay AIS to avoid paying for the services its members desperately need. When AIS’s attempts to negotiate with Anthem failed, AIS was forced to terminate the parties’ agreement and file this action to recover payment for the valuable services it has provided – and continues to provide – to Anthem’s members.

But instead of simply paying AIS in accordance with the parties’ agreement, Anthem responded with a counterclaim, asserting AIS breached the parties’ agreement by terminating it, along with a host of baseless and evidence-free affirmative defenses.

The Court should grant AIS summary judgment on its breach of contract and declaratory judgment claims, as well as on Anthem's meritless counterclaim and affirmative defenses.

### **STATEMENT OF UNDISPUTED MATERIAL FACTS**

#### **A. AIS Provides Specialized And Critical HIT Services.**

1. **HIT.** Home infusion therapy, or HIT, via intrathecal pump involves the continuous infusion of medication through pain pumps that are surgically-implanted into a patient's spine. Exhibit ("Ex.")<sup>1</sup> 11 ("Sobecki Tr.") at 46:18-47:25; Ex. 12 ("Timmerman Tr.") at 90:16-91:13; Ex. 13 at AIS00079939.

2. A patient generally receives this type of therapy at home – rather than in an inpatient facility like a hospital. Ex. 9 ("Henning Tr.") at 147:12-19.

3. HIT offers substantial and well-recognized benefits for patients. Ex. 10 ("Kovacs Tr.") at 76:5-11; Ex. 13 at AIS00079942.

4. Because the medication is delivered directly through the intrathecal pump, intrathecal HIT patients can control their symptoms without experiencing the side effects of high-dose oral opioids. Kovacs Tr. at 76:5-11; Ex. 13 at AIS00079939.

5. Typically, an accredited compounding pharmacy is responsible for providing HIT services. Unlike a standard pharmacy, which "mass produc[es]" commercial patient medications, a compounding pharmacy creates and develops one-of-a-kind specialized medications designed to meet the "unique needs of an individual patient." Ex. 50.

6. Using advanced and technical processes, a compounding pharmacy can customize a patient's medication to account for specific dosage, strength, content, and sterility

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<sup>1</sup> "Exhibits" refer to the exhibits attached to the declaration of Paul Werner submitted in support of this motion.

requirements. But to do so, the pharmacy must make substantial “investment[s] in equipment and training” to prepare each patient’s unique medication “safely and efficiently.” Ex. 50.

7. A compounding pharmacy must also obtain special accreditations and comply with additional state and federal regulations. *Id.* Given these high costs and additional burdens, less than 13% of pharmacies in the United States specialize in compounding, and even fewer provide HIT. Ex. 50.

8. ***AIS’s Care And Services.*** AIS is a fully-accredited, compounding pharmacy that operates in a specialized area of HIT. Ex. 14.

9. AIS develops and dispenses patient-specific compounded medications that are infused via implanted intrathecal pumps into a patient’s spinal column. Sobecki Tr. at 82:18-83:9.

10. This type of therapy is high risk and requires significant investment in operations to account for additional sterilization requirements and compounding procedures. *See, e.g.,* Ex. 15 at AIS00071097-98.

11. Physicians often prescribe intrathecal pumps for patients to reduce chronic pain and muscle spasticity associated with such illnesses and medical conditions as cancer, cerebral and spinal cord injuries, failed back surgery, chronic pancreatitis, cerebral palsy, multiple sclerosis, strokes, and other systemic conditions. *See, e.g.,* Ex. 13 at AIS00079939-40. The pumps are surgically implanted and then filled with the carefully compounded medication that the pump infuses continuously through a catheter inserted into the patient’s spinal column. Sobecki Tr. at 46:18-47:25.

12. The “infusion” or “administration” of the medication refers to the continuous release of AIS’s medication as it proceeds through a patient’s pump. *Id.* at 116:1-15; Kovacs Tr.

at 74:21-76-3. The pump can infuse AIS's medication continuously for weeks or months at a time. Timmerman Tr. at 93:11-14.

13. AIS invests substantial capital and resources to provide patients stable, sterile, effective, and high-quality compounded medications that will safely operate with their pumps. *See, e.g.*, Ex. 15 at AIS00071097-98.

14. Indeed, intrathecal HIT is one of the most highly-regulated therapies in the United States, and for good reason. *See, e.g.*, Ex. 8 ("Forshage Tr.") at 160:14-161:3. Because the patient medications are directly administered into a patient's spine, the medication must be 100% sterile; any impurities can result in serious illness or death.<sup>2</sup>

15. Thus, AIS maintains state of the art clean rooms, only allows licensed pharmacists to compound its medications, uses full body sterile garb for all cleanroom personnel, and requires multiple redundant tests to ensure medication sterility and accuracy. *See, e.g.*, Ex. 50; *see also* Ex. 15 at AIS00071097-98.

16. In addition to preparing patient-specific medications, AIS invests substantial resources to provide patients with ongoing care and additional bespoke services. *See, e.g.*, Ex. 15 at AIS00071085-94. These services include continuous patient monitoring, professional pharmacy services, care coordination, nursing services, billing and financial support services, and administrative services. *Id.*

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<sup>2</sup> The consequences of dispensing tainted medication are serious – and deadly. In what became one of the worst public health crises in our nation's history, a different compounding pharmacy dispensed contaminated drugs that were administered to patients directly to their spinal columns. Ex. 49. The result: 751 patients fell ill with fungal meningitis, resulting in over 64 patient deaths as well as 14 criminal indictments against the pharmacy and its executives. *Id.*

17. For example, AIS provides patients with 24/7/365 telephone access to pharmacists and nurses for treatment- and billing-related support, as well as educational materials. *See, e.g.*, Ex. 5 (“Aborne Tr.”) at 52:21-53:15.

18. AIS also employs a team of nurses that provide in-patient care and an additional team of AIS representatives that coordinates provider and patient activities. *See, e.g.*, *id.* at 64:15-67:14.

19. AIS assumes care for a patient at the direction of the treating physician, who sends AIS a physician order documenting the prescribed plan of care, including the medication and duration of treatment. *See, e.g.*, Ex. 16 at AIS\_VA00000333.

20. Before beginning their first treatment with AIS’s medication, a patient will typically execute a consent form to receive AIS’s medication and services as well as a financial responsibility form agreeing to pay amounts not covered by insurance. *See, e.g.*, Ex. 17 at AIS\_VA00000327; Ex. 18 at AIS\_VA0000330-332. Patients expressly “[REDACTED] [REDACTED]” Ex. 17.

21. When it receives a physician order from a patient’s treating physician, AIS creates the patient’s medication, and prepares a compounding record detailing its compounding directions and processes, quality control measures, and supplies used. *See, e.g.*, Ex. 19; Aborne Tr. at 105:8-17.

22. It then “dispenses,” or processes and delivers, the patient’s medication and documents that event with a tracked delivery ticket. *See, e.g.*, Ex. 20. AIS also provides new patients with a “Welcome Packet” detailing AIS’s care and services, in addition to consent and financial responsibility forms. Aborne Tr. at 75:8-17.

## **B. AIS Agrees To Provide Intrathecal HIT Services To Anthem Members.**

23. ***The Parties' 2020 Provider Agreement.*** Recognizing the value and quality of AIS's therapies, Anthem entered a provider agreement with AIS in February 2020, effective April 1, 2020. Ex. 1 ("2020 Provider Agreement").

24. The 2020 Provider Agreement was a standard form contract that Anthem drafted and offered to AIS. Henning Tr. at 22:19-23:1 & 108:25-109:4.

25. Prior to entering any agreement with a provider, Anthem would conduct diligence to ensure it understood the provider's services. Henning Tr. at 71:25-72:8.

26. Anthem thus diligenced AIS and understood the nature of its care and services. Timmerman Tr. at 257:13-258:6; Henning Tr. at 71:25-72:19.

27. Under the 2020 Provider Agreement, AIS was directed to bill Anthem for three distinct types of claims: per diems, drugs, and nursing/ other services. 2020 Provider Agreement at ANTM 00001384-86.

28. ***The Per Diem Reimbursement Model.*** Anthem agreed to pay for the specialized HIT care and services provided to its members in accordance with the industry standard per diem reimbursement model established by the NHIA and restated in the parties' 2020 Provider Agreement. 2020 Provider Agreement at ANTM\_ 00001385-86; Ex. 22 ("NHIA Standards") at AIS00079073-78 & AIS00079086; Ex. 7 ("Castellanos Tr.") at 122:22-123:21.

29. The NHIA Standards are the “ [REDACTED]  
[REDACTED]” Henning Tr. at 90:24-91:2.

30. Anthem's Director of Network Management for HIT and other witnesses from Anthem's HIT contracting department repeatedly acknowledged that Anthem considered and referenced the NHIA Standards in negotiating with AIS. Sobecki Tr. at 87:16-88:10 (stating

Anthem interpreted S9328 in the parties' 2020 Provider Agreement in accordance with the "████████" and "████████"); Henning Tr. at 39:16-21; Ex. 23.

31. Under this model, a HIT provider bills a negotiated per diem rate for each day a patient has "access" to a "prescribed therapy" – that is, the medication and services. NHIA Standards at AIS00079072.

32. A HIT provider commences billing the per diem the day the prescribed therapy is initiated – the day the patient is put "on service" with the HIT provider – and ceases on the day the therapy is discontinued. Aborne Tr. at 50:19-51:14; NHIA Standards at AIS00079072.

33. For patients with intrathecal pumps, the per diem applies each day the pump administers – that is, infuses – medication because the patient has access to the medication and services every day. Aborne Tr. at 240:1-23; Timmerman Tr. at 159:12-160:9; Sobecki Tr. at 116:1-15.

34. Consistent with the purpose of HIT to allow patients to go about their daily lives while receiving critical treatment, there need not be any daily interaction between the HIT provider and patient for a per diem to apply. *See, e.g.*, Aborne Tr. at 54:12-55:1 & 103:22-104:1; NHIA Standards at AIS00079072.

35. By design, the per diem provides a "fair return" to ensure patients have "continued access to these therapies." NHIA Standards at AIS00079073.

36. Even on days there are not specific interactions between patient and provider, the HIT provider maintains continued responsibility for the patient and incurs costs related to such responsibility because the patient continues to receive infusions of the HIT provider's medication. Aborne Tr. at 91:18-93:15; *see* NHIA Standards at AIS00079072. Those costs

include maintaining nurses and personnel to address patient questions and issues if and when they arise. NHIA Standards at AIS00079075.

37. The per diem is intended to compensate HIT providers for the significant costs they incur to provide ongoing infusion therapies and related services. 2020 Provider Agreement at ANTM\_00001384-86; NHIA Standards at AIS00079072-78.

38. The per diem is thus the only form of compensation under the 2020 Provider Agreement that AIS would receive for its compounded medication and related care and services.<sup>3</sup> 2020 Provider Agreement at ANTM\_00001384-86; Kovacs Tr. At 112:2-115:7.

39. AIS bills its per diem claims under Healthcare Common Procedure Coding System (“HCPCS”) Code S9328, which specifically applies to intrathecal HIT providers, like AIS. *See, e.g.*, 2020 Provider Agreement at ANTM\_00001385-86.

40. Code S9328 bundles multiple covered services into one per diem charge. 2020 Provider Agreement at ANTM\_00001385-86; Sobecki Tr. at 96:5-8.

41. A provider may bill that code whenever it provides one of the covered services, including the administration of the drug itself. *See, e.g.*, Aborne Tr. at 54:12-55:1 & 103:22-104:1; NHIA Standards at AIS00079072-78.

42. Code S9328 includes “ 

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<sup>3</sup> While AIS is separately compensated for the drug powder, or the raw material that is part of its compounded solutions, that payment is not intended to and does not cover the cost of compounding, the final compounded medication, or the access to care and services AIS offers. 2020 Provider Agreement at ANTM\_00001386 (noting “” under S9328); Aborne Tr. at 59:10-60:13. Those costs are covered only by the per diem. 2020 Provider Agreement at ANTM\_00001386; Aborne Tr. at 59:10-60:13. The powders are just the “ingredients” of the “cake” – unique, compounded medications – that AIS creates on an individualized basis for patients.

████████” 2020 Provider Agreement at ANTM\_00001386; *see also* NHIA Standards at AIS00079086.

43. As set forth in the parties’ 2020 Provider Agreement, services and costs that fall under Code S9328 include:

- ***Administration of AIS’s medications***, which occurs through daily infusions;
- ***Professional pharmacy services***, including dispensing medications, sterile compounding, patient counseling, developing and implementing care plans, storing and disposing of infectious waste, and maintaining accreditation and insurance;
- ***Administrative services***, such as coordinating benefits with insurers, performing billing and collection activities, maintaining inventories, or engaging in quality assessment and improvement activities;
- ***Care coordination***, including clinical coordination with medical personnel, providing a dedicated infusion team with 24/7 availability for questions and/or problems , and developing and monitoring of nursing care plans;
- ***Supplies and equipment***, including equipment maintenance and repair and providing necessary supplies; and
- ***Other support costs***, including wages, salaries, benefits, and taxes, research and development costs, and other overhead and operational expenses.

2020 Provider Agreement at ANTM\_00001385-86 (describing services covered under S9328); NHIA Standards at AIS00079072-78 (same).

44. Anthem uses the NHIA Standards and “████████” to define the services covered by Code S9328, where those services are not explicitly defined in the parties’ agreement. Sobecki Tr. 87:12-88:10.

45. Anthem does not dispute AIS provides these services, including its compounded medications and daily access to its support services. Henning Tr. at 58:7-59:5 & 72:10-19; Sobecki Tr. at 83:10-85:11; Timmerman Tr. at 137:2-144:5; Ex. 24 at AIS00079936.

46. As the parties' 2020 Provider Agreement makes clear, the per diem is the *only* method by which AIS is paid for both these services and its compounded medications. 2020 Provider Agreement at ANTM\_00001384-86; Kovacs Tr. At 112:2-115:7.

47. In other words, if AIS is not paid the per diem, Anthem does not pay it for “████████” including “████████” “████████,” and “████████” its patients. Kovacs Tr. at 112:2-115:23; 2020 Provider Agreement at ANTM\_00001385-86.

48. Without the per diem, AIS would, according to Anthem, “████████” “████████” but Anthem's members “████████” “████████” and access to AIS's ongoing care and services. Kovacs Tr. at 112:2-115:23.

49. AIS is thus dependent on compensation via the per diem to provide its medications and services to patients. As another home infusion provider explained to Anthem, “████████” to deliver HIT “████████.” Ex. 25 ANTM\_R\_00024159 ¶ 2.

50. Under the 2020 Provider Agreement, AIS was entitled to bill Code S9328 for each day a drug was “████████” – that is, “infused.” 2020 Provider Agreement at ANTM\_00001385 (“████████” and “████████”)).<sup>4</sup>

51. There was only one exception: Anthem would not pay AIS a per diem on the day a patient's intrathecal pump was refilled in a physician's office. 2020 Provider Agreement at

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<sup>4</sup> See also Timmerman Tr. at 159:12-160:9 (testifying “████████”); Sobecki Tr. at 116:1-15 (testifying “████████” means “████████”); Henning Tr. at 147:12-148:5 (testifying AIS's drugs are “████████”); Ex. 30 at AIS00080520 (stating intrathecal infusion pumps “████████” medication to a patient); OXFORD DICTIONARY, ADMINISTER, available at <https://www.oxfordlearnersdictionaries.com/us/definition/english/administer?q=administer> (Defining “administer” as the act of “giv[ing] drugs, medicine, etc. to somebody”).

ANTM\_00001391 (stating under “[REDACTED],” “[REDACTED]”  
[REDACTED]”) (emphasis added);  
Ex. 26 at ANTM\_00019254.

52. But as Anthem’s Director of Network Management confirmed, “[REDACTED]  
[REDACTED]  
[REDACTED]”

Ex. 26 at ANTM\_00019254; *see* Ex. 27 at ANTM\_00007400  
(confirming Anthem understood AIS would bill a daily per diem after the pump was refilled in a physician’s office); Ex. 28 at ANTM\_00024287 (same); Ex. 29 at ANTM\_00011968 (same).  
That makes perfect sense given the per diem is intended to compensate AIS for the cost of daily infusions of medication and ongoing oversight, care, and support services.

53. AIS’s drugs are administered in a patient’s home no matter where a pump is refilled. Kovacs Tr. At 115:18-23.

54. After a pump is refilled, it takes 48-72 hours for that medication to begin to be infused into the patient’s body. Aborne Tr. at 126:19-127:9. By the time the medication enters the patient’s spinal fluid, the patient is at home.<sup>5</sup> *Id.*

55. As a result, and as intended, Anthem’s members “[REDACTED]  
[REDACTED].”

Kovacs Tr. at 115:18-23 (emphasis added); Aborne Tr. at 240:1-23.

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<sup>5</sup> Reflecting the reality that patients receive infusions of its medications at home, AIS has always indicated “place of service 12” – home – in the claims that it submitted to Anthem. *See* Aborne Tr. at 126:18-127:9, 131:19-132:18 & 236:1-10; Ex. 21 at AIS\_VA00000321. In the rare event that AIS’s medications are administered in an in-patient hospital setting, the hospital informs AIS of the in-patient treatment. Aborne Tr. at 135:8-136:20.

56. Consistent with the parties' 2020 Provider Agreement and industry standards, Anthem has always understood "██████████" Ex. 31, at ANTM\_R\_00018292; Ex. 32 at ANTM\_R\_00010450 (explaining "██████████  
██████████  
██████████").

57. Anthem's Medical Director, Dr. Ayms Lang, and an independent Medical Director, confirmed, AIS's billing was proper: " [REDACTED]  
[REDACTED]  
[REDACTED]" Ex. 33 at ANTM\_00024731 (emphasis added); Ex. 34 at ANTM\_00024030 (noting Anthem " [REDACTED]  
[REDACTED]" (emphasis added)).

58. Consistent with that understanding, Anthem knew that the majority of AIS's members received refills for their intrathecal pumps in a physician's office. Sobecki Tr. at 108:2-8.

59. AIS's expert witness, David Franklin, who actually drafted Code S9328 and the per diem reimbursement model, has concluded that AIS's per diem billing under S9328 was entirely appropriate and consistent with the Code's clear terms and underlying purpose. Ex. 47 ("Franklin Report") at 15 ¶ 54.

60. As Mr. Franklin opined, AIS was required to bill HIT under Code S9328 by HIPAA because Code S9328 is the most accurate code to describe intrathecal HIT. Franklin Report at ¶ 6; NHIA Standards at AIS00078981.

61. AIS's second expert witness, Peter Dressel, likewise, reviewed AIS's claims, and determined AIS's HIT services were properly billed in accordance with the NHIA Standards and supported by its claim documentation. Ex. 48 ("Dressel Report") at 10-13.

62. ***Nursing Services.*** Under the 2020 Provider Agreement, AIS billed separately for nursing services, including visits for pump refills, and medications. 2020 Provider Agreement at ANTM\_00001384-85; NHIA Standards at AIS00079079-80.

63. ***Drugs Services.*** Anthem agreed separately to reimburse AIS for its drug claims at the rate set by the 2020 Provider Agreement for a specific drug, either at [REDACTED] above the Average Sales Price as published in the "ASP Drug Pricing File," or at [REDACTED] of the Average Wholesale Price of the drug, as applicable. 2020 Provider Agreement at ANTM\_00001384-91 (explaining AIS was to bill for the "[REDACTED]," "[REDACTED]," and "[REDACTED]" separately).

64. As noted above, AIS's "drug claims" refer to payment for the raw material – the drug powder – used in AIS's compounded medications. 2020 Provider Agreement at ANTM\_00001386 (noting "[REDACTED]" under S9328); Aborne Tr. at 59:10-60:17.

65. It is *not payment for compounding itself*, for the final compounded medication, or for any of the costs that AIS incurs to provide its array of additional care and services to Anthem's members, which are recovered through the per diem. *Id.*

66. ***Amendments.*** The 2020 Provider Agreement allowed Anthem unilaterally to amend the agreement. 2020 Provider Agreement at ¶ 9.1, ANTM\_00001260.

67. The only way AIS could "[REDACTED]" to such an amendment was for it to "[REDACTED]" before the amendment took effect. *Id.*

68. Following the execution of the 2020 Provider Agreement, AIS began providing care to over 1,700 Anthem members. *See generally*, 2020 Provider Agreement.

**C. AIS Rejects Anthem’s Attempt To Amend The Parties’ Agreement To Receive AIS’s Medications And Care For Free.**

69. Almost as soon as the parties entered the 2020 Provider Agreement, Anthem began systematically undermining the parties’ contract to deny AIS the benefit of its bargain.

70. Specifically, seven months after entering the agreement with AIS, Anthem unilaterally amended it to reduce the reimbursement rate for per diem claims from [REDACTED].  
Ex. 2, November 2020 Amendment, at AIS00000666.

71. Then, following “[REDACTED]” from AIS’s competitors, Ex. 31 at ANTM\_R\_00018292, Anthem issued a unilateral amendment that appeared to threaten AIS’s per diem payments entirely. *See* Ex. 3 (“April 2021 Amendment”).

72. In its unilateral April 2021 Amendment, Anthem sought to reduce payment of per diems by apparently conditioning the site of the patient’s refill. *Id.* at ANTM\_R\_00042365. It proposed that, “[REDACTED]  
[REDACTED].” *Id.*

73. In other words, under the April 2021 Amendment, Anthem now contends that it sought to prevent AIS from ever billing the per diem by arbitrarily conditioning the per diem based on the site of refill – even though the plain language of Anthem’s amendment provides two separate pathways to payment: refilling a pump or administering medications in a patient’s home. *Id.*

74. Under Anthem’s current interpretation of the amendment, AIS could not bill the per diem where, as is almost always the case in HIT, a treating physician directs that a patient’s pump be refilled in the clinic as opposed to the home based on patient safety and wellness. *See* Forshage Tr. at 130:12-132:15.

75. As Anthem testified, AIS cannot control where a treating physician directs a patient to receive refills or otherwise compel a patient to receive refills in a particular location. Timmerman Tr. at 248:18-249:3.

76. Nevertheless, Anthem expected AIS to “” the cost and, if necessary, provide the service and drugs for free. Kovacs Tr. at 113:2-115:23.

77. After years of futile efforts to work with Anthem on claims processing issues and providing free care to patients, pursuant to the parties' contract, AIS terminated the 2020 Provider Agreement to object to the April 2021 Amendment. Ex. 35 at ANTM R 00045314-15.

” *Id.* at ANTM R 00045314 ¶2.

79. AIS was clear that Anthem's proposal that "“

” threatened to “

” and was a non-starter. *Id.* at ANTM\_R\_00045315 ¶ 2.

80. Anthem understood that AIS expressly rejected any arrangement in which

“**It is the responsibility of the government to ensure that the public has access to information on all matters of public importance, so that they may participate fully in its development.**”

#### **D. Anthem Blocks AIS's Ability To Bill Claims.**

81. While Anthem was working to chip away at its payment obligations for drugs and HIT services, it failed to process and adjudicate AIS's claims as well. That is entirely consistent with Anthem's treatment of providers nationwide.

82. For example, the New Hampshire Hospital Association found that Anthem owes the state’s hospitals over \$300 million in unpaid claims and had failed to pay over half the claims submitted to it. Ex. 51.

83. In many cases, Anthem rejects claims under broad denial codes that demand unnecessary prior authorizations – or an unending cycle of unspecified medical records – then denies the claims as untimely because they are not “clean.” *Id.*

84. Anthem has used the same playbook across the United States. The Georgia state insurance commissioner fined Anthem \$5 million for failing to pay claims in a timely manner. Ex. 52.

85. Virginia hospitals have also alleged Anthem owes them hundreds of millions in unpaid claims. *Id.* And eleven Indiana hospitals have alleged Anthem requested unspecified medical records for 60-70% of their claims. *Id.*

86. As a result, “complaints about Anthem extend from sea to shining sea, from New Hampshire to California.”<sup>6</sup> In 2021, Anthem failed to pay *more than half of its claims* – putting hospitals, doctors, and patients in an “untenable situation” – while netting \$3.5 billion in profits in the first half of 2021.

87. Anthem’s treatment of AIS was no different. Anthem inconsistently processed and paid AIS’s claims. Anthem failed to process many of AIS’s claims at all, leading to a backlog of claims in every state in which AIS contracted with Anthem (including Virginia). Timmerman Tr. at 274:1-278:5; Ex. 37 at ANTM\_00060414-44.

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<sup>6</sup> Jay Hancock, *Major Insurers Running Billions of Dollars Behind on Payments to Hospitals and Doctors*, KKF HEALTH NEWS, available at [Major Insurers Running Billions of Dollars Behind on Payments to Hospitals and Doctors - KFF Health News](https://www.kff.org/health-reform/policy-analysis/major-insurers-running-billions-of-dollars-behind-on-payments-to-hospitals-and-doctors/).

88. Even where AIS was able to submit timely claims, Anthem refused to process and pay them. Thus, Anthem improperly withheld millions of dollars from AIS for years. Ex. 36 at ANTM\_00025516-17.

89. Nevertheless, Anthem and AIS continued to discuss the submission process for AIS's claims and work together to identify a mutually agreeable claim submission model and process. Ex. 44 at ANTM\_R\_00018834.

90. As Anthem acknowledged in May 2022, “  
[REDACTED]  
[REDACTED].” Ex. 37 at ANTM\_00060415

¶ 6.

91. AIS and Anthem continuously worked to address Anthem's claims processing and payment issues, including for purported timely filing and other denials, through 2022 and into 2023. Ex. 36 at ANTM\_00025516.

#### **E. The December 2021 Amendment.**

92. Following AIS's termination of the 2020 Provider Agreement, and recognizing the tremendous value of its therapy, Anthem negotiated a new amendment with AIS.

93. Simon Castellanos, AIS's CEO, met with Anthem's contracting team. Castellanos Tr. at 174:19-175:23 & 179:9-19.

94. After negotiations with Leah Timmerman, Anthem's Staff Vice President of National Healthcare Networks, Anthem agreed to continue to pay AIS the daily per diem as long as AIS worked with Anthem to convince doctors and patients to have the patients' pumps refilled in their homes rather than a physician's office. Castellanos Tr. at 174:19-175:23 & 179:9-19.

95. Accordingly, the parties negotiated a new amendment with the intent that AIS could continue to bill the per diem daily because its medication were administered continuously in the patient’s home, but would not bill for the date the pump was refilled in a physician’s office. Castellanos Tr. at 183:22-186:18. AIS would also work with Anthem to move the patient’s pump refill to the home as well. *Id.* at 174:19-175:23.

96. Based on Anthem’s negotiations and representations, the parties ultimately signed a new amendment to the 2020 Provider Agreement, effective December 15, 2021. Ex. 4, (“December 2021 Amendment”). The December 2021 Amendment provided that “[REDACTED] [REDACTED]” if AIS’s drugs were “[REDACTED] [REDACTED].” *Id.* at AIS00030320.

97. It further provided that “[REDACTED] [REDACTED]” *Id.* at AIS00030326 (emphasis added).

98. Because AIS’s drugs were “[REDACTED] in the patient’s home, AIS was authorized to bill Anthem for each day after the pump was refilled if the refill occurred in the physician’s office. Aborne Tr. at 241:18-244:16.

#### **F. Anthem Confirms AIS’s Billing Practices Are Proper.**

99. For years, Anthem serially audited and investigated AIS’s claims to ensure AIS properly billed under the agreements and amendments. With each review, Anthem confirmed AIS could bill the per diem for its HIT, which included its compounded medications and the ongoing care AIS provided to Anthem’s members.

100. Prior to the December 2021 Amendment, Anthem directed EquiClaim, its third-party auditor, to analyze AIS’s drug and Code S9328 claims. Ex. 38 at AIS00079960-61.

EquiClaim analyzed hundreds of claims, including for when “[REDACTED]” and had refills performed “[REDACTED]” *Id.* at AIS00079960 ¶ 1.

101. Following its audit, EquiClaim came to the same conclusion that Anthem’s Medical Director, Director of Network Management, and other employees had already reached: “[REDACTED].” Ex. 39 at ANTM\_00018211.

102. As a result, EquiClaim closed its investigation of AIS’s claims and determined that AIS should receive approximately \$1.9 million in per diem claims. *Id.*

103. Following the December 2021 Amendment, Anthem’s Special Investigation Unit (“SIU”) – which is tasked with investigating providers for possible waste, fraud, and abuse – investigated AIS’s billing, including its billing under code S9328. Anthem’s SIU placed AIS on prepayment review from December 18, 2021, through April 1, 2022, meaning it manually reviewed AIS’s claims and supporting documentation. Ex. 40 at ANTM\_00054841.

104. Anthem’s SIU also requested and reviewed the parties’ contracts and medical records and could even speak directly to Anthem members. Ex. 6 (“Cahoon Tr.”) at 78:6-8, 83:19-84:2 & 91:22-24.

105. Anthem’s SIU analyzed AIS’s claims and found that they were properly submitted. Ex. 41 at ANTM\_00055426-29. Anthem concluded that Code S9328 “[REDACTED]” and that AIS’s documentation supported its per diem billing. *Id.* at ANTM\_00055427-28.

106. Finding AIS’s claims to be entirely proper under the 2020 Provider Agreement, Anthem took AIS’s S9328 claims off prepayment review on February 11, 2022. Ex. 42 at ANTM\_00024934; Cahoon Tr. at 144:20-25.

107. Anthem's SIU has never found that AIS committed waste, fraud, or abuse. Cahoon Tr. at 156:14-24.

#### **G. Anthem Refuses To Pay AIS, Forcing AIS To Initiate This Action.**

108. In accordance with the December 2021 Amendment, AIS billed Anthem for its drugs and per diems while working in good faith to transition patients to a home refill of their intrathecal pumps. AIS hired and trained nurses and reached out to physicians regarding the site of the pump refills. Ex. 43 at AIS00052361-62; Aborne Tr. at 160:14-18.

109. While a handful of patients transitioned to a home-refill model, the overwhelming majority of the physicians refused to transition their patients for medical reasons. Ex. 43 at AIS00052362; Ex. 44 at ANTM\_R\_00018834; Castellanos Tr. at 195:2-195:9.

110. Among other issues, physicians resisted a home-refill model for medical and liability reasons. That change would force them to take on the regulatory and financial risks AIS traditionally bore in providing compounded medications and ongoing services and care. Ex. 43 at AIS00052362; Ex. 44 at ANTM00018834; Castellanos Tr. at 195:2-195:9.

111. It would also put patients at risk. Most of these patients are very sick and need to be seen in the clinic given the risks inherent in HIT therapy. *See* Forshage Tr. at 130:4-132:15. The patients are receiving highly concentrated opioids. Clinics are more sterile and better equipped to handle medical emergencies than a patient's home. If something goes wrong in the home, the patient could die; whereas, in the physician's office, medical staff and resources are immediately available. *See* Ex. 43.

112. AIS explained the physicians' reluctance to Anthem, and repeatedly attempted to engage with Anthem to discuss the issue. Ex. 43 at AIS00052361-62; Ex. 44 at ANTM\_R\_00018834.

113. Instead of working with AIS as it said it would do, Anthem breached the parties' agreement. It stopped paying AIS's claims – even though it has never found that AIS committed fraud, waste, or abuse, or even that it breached the contract. Cahoon Tr. at 156:20-24; Sobecki Tr. at 139:16-140:8; Timmerman Tr. at 247:19-249:20 (stating Anthem expected the physician to compensate AIS for the medications AIS provided Anthem's members).

114. Following Anthem's failure to pay AIS, AIS initiated this action while maintaining its continuity of care obligations to Anthem's members. *See generally*, Complaint, ("Cmplt.") Dkt. 1. AIS's care to these patients remains ongoing today, even though Anthem has failed and refused to pay for that care.

115. To streamline the litigation and avoid the individual review of tens of thousands of claims across Anthem's footprint, the parties agreed on a sample population of disputed medical claims. Ex. 46 at AIS00067537-40.

116. Based on the sample population, AIS's expert witnesses concluded that AIS's HIT services were properly billed in accordance with the NHIA Standards and supported by its claim documentation. Franklin Report at 15-16; Dressel Report at 10-13.

117. Peter Dressel, AIS's damages expert, extrapolated the damages suffered by AIS from the Virginia sample claims, resulting in an underpayment of [REDACTED], plus pre-judgment and post-judgment interest on that amount. Dressel Report at 13-16.

### **STANDARD**

This motion is governed by familiar standards. Courts grant summary judgment where there is "no genuine issue as to any material fact" and the movant is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A mere "scintilla of evidence in support" of the non-moving party's claims will not spare a claim

from summary judgment. *Anderson*, 477 U.S. at 252; see *Progressive Am. Ins. Co. v. Jireh House, Inc.*, 608 F. Supp. 3d 369, 372 (E.D. Va. 2022).

## **ARGUMENT**

## **I. AIS Is Entitled To Summary Judgment On Its Breach Of Contract Claim.**

**A. Anthem Improperly Failed To Pay AIS's Pre-Amendment Per Diem Claims.**

AIS is entitled to summary judgment on all pre-amendment per diem claims because there is no genuine dispute that Anthem breached the 2020 Provider Agreement by failing to pay AIS's claims. Fed. R. Civ. P. 56. A breach of contract claim requires a plaintiff to show that a defendant breached the parties' agreement, resulting in damages to the plaintiff. *See, e.g., JTH Tax, LLC v. Shahabuddin*, 477 F. Supp. 3d 477, 481 (E.D. Va. 2020); *Enomoto v. Space Adventures, Ltd.*, 624 F. Supp. 2d 443, 449 (E.D. Va. 2009). In interpreting a contract, courts give effect to the plain meaning of the parties' words. *Wilson v. Holyfield*, 227 Va. 184, 187 (1984).

Here, Anthem agreed to pay AIS for per diem claims submitted under Code S9328. 2020 Provider Agreement at ANTM\_00001384-86 (instructing AIS to “[REDACTED]” for home infusion therapy under code “[REDACTED]”); Franklin Report at 3; *supra* at pages 7-13. The parties’ agreement clearly states Anthem will pay a per diem for each “[REDACTED]” “[REDACTED]” There is no disagreement that “[REDACTED]” means “[REDACTED]” – which makes sense, given that the plain dictionary meaning of the word “administered” is to “give drugs, medicine, etc. to somebody.” 2020 Provider Agreement at ANTM\_00001385; Aborne Tr. at 240:1-23; Timmerman Tr. at 159:12-160:9; Sobecki Tr. at 116:1-15.<sup>7</sup>

<sup>7</sup> OXFORD DICTIONARY, ADMINISTER, *available at* <https://www.oxfordlearnersdictionaries.com/us/definition/english/administer?q=administer>.

Anthem repeatedly confirmed this plain text understanding of the contract in internal emails and external communications to AIS. *Supra* at pages 12-13. As Anthem's head of HIT contracting, who negotiated the agreement with AIS, repeatedly explained, "[REDACTED]

[REDACTED]  
[REDACTED]" because "[REDACTED]  
[REDACTED]

[REDACTED]" Exs. 26 at ANTM\_00019254 & 29 at ANTM\_00011968.

There is no dispute that AIS properly billed Code S9328 for each day the patient had access to its medication as it infused through the pump, as well as for providing ongoing patient care and services. Franklin Report at 15-16; Dressel Report at 10-13. AIS is entitled to payment on its pre-amendment claims.

**B. It Is Undisputed Anthem Improperly Failed To Pay AIS's Post-Amendment Per Diem Claims.**

The record confirms that Anthem also breached its payment obligations to AIS by denying claims and recouping payments for per diem claims billed after the December 2021 Amendment. Like the 2020 Provider Agreement, the December 2021 Amendment is clear that per diems are not payable *only if* AIS's drugs were "[REDACTED]  
[REDACTED]" December 2021 Amendment at AIS00030320 (emphasis added). But it is undisputed AIS's medications are administered in the home. Aborne Tr. at 240:1-23; Timmerman Tr. at 159:12-160:9; Sobecki Tr. at 116:1-15. AIS is therefore entitled to payment for these claims.

Anthem's addition of the word "[REDACTED]" to the December 2021 Amendment does not change the plain meaning of the amendment. *Amchem Prod., Inc. v. Newport News Cir. Ct. Asbestos Cases*, 264 Va. 89, 98 (2002) (explaining the court would not add words to the

days if a member ever receives any services in a physician's office. *Id.* at AIS00030326.

Because it is undisputed that AIS's medications are administered in the home, AIS is entitled to payment for its post-amendment per diem claims.

### C. It Is Undisputed Anthem Improperly Failed To Pay AIS's Drug Claims.

The 2020 Provider Agreement required Anthem to pay AIS for the raw drug powder AIS used to compound its medications. 2020 Provider Agreement at ANTM\_00001384-5. Anthem does not dispute that it has failed to do so. *See, e.g.*, Dressel Report at 13.

To avoid paying AIS, Anthem asserts it is not required to pay for any drug shipped to a physician's office, pointing to an exclusion in the 2020 Provider Agreement that states

<sup>8</sup> In other words, the word “[REDACTED]” in the amendment phrase “[REDACTED] outside the home is properly read as “[REDACTED] outside the home. December 2021 Amendment at AIS00030320.

Provider Agreement at ANTM\_00001391 (emphasis added). But this boilerplate exclusion from Anthem’s form contract does not apply to AIS’s drug claims for its unique therapies (even though it could apply to some of Anthem’s other contracts with other providers for different medications). That is because AIS’s drug claims are not for its finished, compounded medications; they are for the *raw powder* that AIS uses in compounding – which are not shipped anywhere. Aborne Tr. at 59:25-60:17. Thus, Anthem’s touted exclusion does not apply to AIS’s drug claims.

The record clearly shows that AIS is entitled to payment for its drug claims under the parties’ agreements.

#### **D.      Anthem’s Breaches Have Harmed AIS.**

Anthem’s breaches of the agreement have caused AIS substantial harm. As AIS’s expert witness, Peter Dressel, opined, AIS provided and documented its per diem and drug claims in accordance with NHIA Standards, which are incorporated into the parties’ contract. Dressel Report at 10-13. Yet Anthem refused to pay AIS. *Id.* at 13. Based on Mr. Dressel’s extrapolation of the damages suffered by AIS in the sample claim set, Anthem owes AIS [REDACTED], plus pre-judgment and post-judgment interest.<sup>9</sup> *Id.* at 13-16.

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<sup>9</sup> If the Court were to grant AIS summary judgment on its breach of contract claim, AIS’s unjust enrichment claim would be moot. Cmplt. ¶¶ 183-88. Unjust enrichment is an alternative claim to breach of contract. *Remacle v. Repperio, Inc.*, Case No. 1:17-cv-00434, 2017 WL 11505574, at \*9-10 (E.D. Va. Aug. 25, 2017). AIS included an unjust enrichment claim here because under Anthem’s proposed reading of the December 2021 Amendment, AIS would be providing all of its services to Anthem’s members for free. That reading of the contract would be unconscionable, unenforceable, and would entitle AIS to equitable restitution. *March v. Tysinger Motor Co., Inc.*, Case No. 3:07-cv-508, 2007 WL 4358339, at \*4 (E.D. Va. Dec. 12, 2007) (“As a matter of public policy, Virginia refuses to enforce unconscionable contracts.”); *Gibbs v. Haynes Invs., LLC*, 368 F. Supp. 3d 901 (E.D. Va. 2019).

## **II. AIS Is Entitled To Summary Judgment On Its Declaratory Relief Claim.**

AIS is similarly entitled to summary judgment on its declaratory relief claim related to Anthem's failure to pay AIS's per diem and drug claims. Cmplt. ¶¶ 189-193. In the case of a controversy between two parties, a court may "declare the rights and other legal relations of any interested party." 28 U.S.C. § 2201.

Here, there is an actual controversy between Anthem and AIS regarding whether Anthem must pay AIS for the services AIS provided in accordance with the parties' contract and industry standards. *Supra* at pages 20-22. It must.

## **III. AIS Is Entitled To Summary Judgment On Anthem's Counterclaim.**

AIS is entitled to summary judgment on Anthem's breach of contract counterclaim. Anthem alleges that AIS breached the parties' agreement by immediately terminating the provider agreement without providing continuity of care for its members. Dkt. 41, Answer & Counterclaim ¶¶ 45-55. Not so. Anthem induced AIS to enter the December 2021 Amendment and continued to care for Anthem's members based on fraudulent and material misstatements that it would pay AIS for its costly and vital care, which, in fact, it never had any intention of doing. *Supra* at pages 14-16, 18 & 20-22. As a result, AIS was well within its rights to the terminate the 2019 Provider Agreement immediately. 2020 Provider Agreement at ANTM\_00001258-59. And it is undisputed AIS has fully complied with its continuity of care obligations to Anthem's members. *Supra* at page 22.

But even putting aside that AIS properly terminated the agreement, Anthem has not presented any evidence regarding damages it supposedly suffered as a result of AIS's termination, including any expert testimony at all. That is fatal to Anthem's claim. *Sunrise Continuing Care, LLC v. Wright*, 277 Va. 148, 156 (Va. 2009) ("[P]roof of damages is an

essential element of a breach of contract claim, and failure to prove that element warrants dismissal of the claim.”); *see Vienna Metro LLC v. Pulte Home Corp.*, 786 F.Supp.2d 1076, 1086-88 (E.D. Va. 2011) (granting summary judgment where party failed to prove damages).

#### **IV. There Is No Record Support For Anthem’s Affirmative Defenses.**

Anthem’s affirmative defenses similarly fail to create any genuine issue of material fact sufficient to avoid summary judgment. Anthem raised eleven affirmative defenses to AIS’s complaint. Dkt. 41, Answer & Counterclaims. Anthem has the burden of proof to “put forth a factual basis supporting” each affirmative defense in order to “survive summary judgment.”

*TecSec, Inc. v. Adobe Systems, Inc.*, 326 F. Supp. 3d 105, 109 (E.D. Va. 2018).

Anthem has failed to do so. For example, Anthem presented no evidence of specific claims that are the liability of third parties or subject to any set off (second and seventh defenses), are subject to contractual limitations or any statute of limitations (eighth and ninth defenses), or that are barred by ERISA (tenth defense). Dkt. 41, Answer & Counterclaims, Affirmative Defenses. Anthem has failed to present facts supporting its equitable defenses, including waiver, laches, estoppel, unclean hands, and good faith (defenses three through six), much less explain how those defenses justify Anthem’s failure to pay AIS. *Id.* Anthem never raised its failure to state a claim defense (first defense) in this Court. *Id.* And Anthem has never identified any “additional defenses” that would excuse it from payment (any of which defenses would be untimely in any event). *Id.* As a result, all of Anthem’s affirmative defenses are properly “struck at the summary judgment phase.” *TecSec, Inc.*, 326 F. Supp. 3d at 109; *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993) (stating “this Circuit has noted the affirmative obligation of the trial judge to prevent factually unsupported claims and defenses from proceeding to trial”).

## **CONCLUSION**

The Court should grant AIS's Motion for Summary Judgment.

Date: December 1, 2023

Respectfully submitted,



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